

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
Charlottesville Division**

CYNTHIA B. EVANS,

Plaintiff,

v.

MEDTRONIC, INC.,

Defendant.

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Civil Action No. 3:04cv-97-JHM

ANSWER

Defendant MEDTRONIC, INC. (“Medtronic” or “Defendant”), by counsel, states as follows for its Answer to Plaintiff’s Complaint.

1. The first sentence of Paragraph 1 of Plaintiff’s Complaint contains conclusions of law to which no response by Defendant is required. With regard to the second sentence of paragraph 1, Defendant admits that it is a Minnesota corporation with its principle place of business in Minnesota. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegation concerning Plaintiff’s citizenship, and therefore denies the same. The last sentence of Paragraph 1 is a legal conclusion to which no response by Defendant is required.

2. Paragraph 2 of Plaintiff’s Complaint contains conclusions of law to which no response by Defendant is required.

3. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 3 of the Plaintiff’s Complaint, and therefore denies the same. Defendant further states that the documents attached as Exhibits A and B to the

Plaintiff's Complaint and referenced in Paragraph 3 speak for themselves and any attempts by Plaintiff to characterize them are denied.

4. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 4 of the Plaintiff's Complaint, and therefore denies the same.

5. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 5 of the Plaintiff's Complaint, and therefore denies the same.

6. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 6 of the Plaintiff's Complaint, and therefore denies the same.

7. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegation that any of the products or devices referenced in Paragraph 7 of the Plaintiff's Complaint fractured, and therefore denies the same. Defendant denies that any of the products or devices referenced in Paragraph 7 of the Plaintiff's Complaint malfunctioned or were otherwise defective. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 7 of the Plaintiff's Complaint, and therefore denies the same. Defendant further states that the documents attached as Exhibits C and D to the Plaintiff's Complaint and referenced in Paragraph 7 speak for themselves and any attempts by Plaintiff to characterize them are denied.

8. Defendant denies that any of the products or devices referenced in Paragraph 8 of the Plaintiff's Complaint malfunctioned, failed, or were otherwise defective.

Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 8 of the Plaintiff's Complaint, and therefore denies the same.

9. Paragraph 9 of the Plaintiff's Complaint contains a legal conclusion to which no response by Defendant is required. To the extent a response by Defendant is required, Defendant denies the same.

10. Paragraph 10 of the Plaintiff's Complaint contains legal conclusions to which no response by Defendant is required. To the extent a response by Defendant is required, Defendant denies the same.

11. Paragraph 11 of the Plaintiff's Complaint contains legal conclusions to which no response by Defendant is required. To the extent a response by Defendant is required, Defendant denies the same.

12. Paragraph 12 of the Plaintiff's Complaint contains legal conclusions to which no response by Defendant is required. To the extent a response by Defendant is required, Defendant denies the same, including subparts (a) through (g).

13. Defendant denies that Plaintiff is entitled to any of the relief requested in the "WHEREFORE" paragraph immediately following Paragraph 12 of Plaintiff's Complaint.

14. Defendant denies each and every allegation in the Plaintiff's Complaint that is not specifically admitted herein.

ADDITIONAL DEFENSES

First Additional Defense

1. The Complaint fails to state a claim upon which relief may be granted.

Second Additional Defense

2. The Plaintiff's claims are barred, in whole or in part, by her contributory negligence.

Third Additional Defense

3. The Plaintiff's action is barred by the Restatement (Second) of Torts, Section 402A, Comments j and k, and any Virginia case law upholding and applying those provisions.

Fourth Additional Defense

4. The products Plaintiff refers to in the Complaint conformed to the state-of-the-art for the design and manufacture of such or similar products.

Fifth Additional Defense

5. Plaintiff's claims are barred because the damages alleged by Plaintiff were caused or proximately caused by some person or third party other than Defendant for whom Defendant is not legally responsible.

Sixth Additional Defense

6. Plaintiff's causes of action are barred because the alleged damages resulted from new and independent, unforeseeable, superseding and/or intervening causes unrelated to any conduct of, or product placed in the stream of commerce by, Defendant.

Seventh Additional Defense

7. Plaintiff's causes of action are barred because the alleged damages were not proximately caused by any act or omission of Defendant.

Eighth Additional Defense

8. Plaintiff's claims are barred because her alleged damages were the result of an idiosyncratic reaction by Plaintiff which Defendant could not reasonably foresee.

Ninth Additional Defense

9. Plaintiff's claims are barred because Plaintiff's damages, if they were caused by Defendant's product(s), were caused in whole or in part by misuse, or abnormal or unintended use of the product(s).

Tenth Additional Defense

10. Plaintiff's claims are barred because Plaintiff's damages, if any, were caused by changes and/or alterations to Defendant's products made by persons not within Defendant's control.

Eleventh Additional Defense

11. Plaintiff's claims are barred because Plaintiff's alleged damages were not caused by any failure to warn on the part of Defendant.

Twelfth Additional Defense

12. Defendant provided adequate and complete warnings to Plaintiff's prescribing physicians. Therefore, any claims by Plaintiff for inadequate warnings are controlled by, and barred under, the learned intermediary doctrine.

Thirteenth Additional Defense

13. Plaintiff's claims are barred, in whole or in part, by Plaintiff's failure to assert a safer design for the product(s) at issue.

Fourteenth Additional Defense

14. Plaintiff's action is barred, in whole or in part, by the lack of a defect, since the product(s) alleged to be defective in the Plaintiff's Complaint were properly manufactured in accordance with the applicable standard of care.

Fifteenth Additional Defense

15. Plaintiff's action is barred because the benefits of the relevant product(s) outweighed its risks.

Sixteenth Additional Defense

16. Plaintiff's action is barred because the relevant product(s) was consistent with or exceeded consumer expectations.

Seventeenth Additional Defense

17. Plaintiff's action is barred because, based on the state of scientific, medical, and technological knowledge at the time the product(s) at issue was manufactured, the product(s) was reasonably safe for its normal and foreseeable use at all relevant times.

Eighteenth Additional Defense

18. Plaintiff's claims are barred, in whole or in part, because Defendant complied with all applicable statutes and with the requirements and regulations of the FDA.

Nineteenth Additional Defense

19. Plaintiff's claims are barred by the doctrine of federal preemption.

Twentieth Additional Defense

20. The damages, if any, recoverable by Plaintiff must be reduced by any amount of damages legally caused by her failure to mitigate such damages in whole or in part.

Twenty-First Additional Defense

21. Each item of economic loss alleged in the Plaintiff's Complaint was, or with reasonable certainty will be, replaced or indemnified, in whole or in part, from other sources.

Twenty-Second Additional Defense

22. Defendant expressly denies that any third party engaging in the acts alleged by Plaintiff was acting as Defendant's agent or servant, at the instruction of Defendant, or within Defendant's control. Therefore, to the extent that Plaintiff seeks recovery for the acts or omissions of such third parties, they are barred in whole or in part as a matter of law.

Twenty-Third Additional Defense

23. To the extent Plaintiff seeks to recover for breach of the implied warranty of fitness for a particular purpose, she has failed to state a claim upon which relief may be granted, as she has not alleged a particular purpose for the product(s) at issue aside from its ordinary purpose, or that Defendant or its agents knew or had reason to know of such particular purpose.

Twenty-Fourth Additional Defense

24. Plaintiff's Complaint is barred to the extent that the Plaintiff and/or any third party used the product(s) at issue after they were aware or should have been aware of any alleged defect.

Twenty-Fifth Additional Defense

25. Defendant alleges that, upon information and belief, Plaintiff was fully aware of and informed about the nature of the medical devices and the risks and possible adverse effects pertaining to the surgical procedure performed upon her and the placement of the medical device(s) at issue in this case into the Plaintiff's person, and all injuries, damages or losses, if any, that Plaintiff sustained arose from and were caused by risks of which the Plaintiff was aware. Plaintiff accepted and assumed all such risks. Accordingly, Plaintiff's claims are barred, in whole or in part, by the principles of assumption of risk and informed consent.

Twenty-Sixth Additional Defense

26. Plaintiff's injuries, damages, and/or losses as alleged in the Plaintiff's Complaint were caused by Plaintiff's pre-existing medical conditions, subsequent medical conditions, and/or natural course of conditions for which Defendant is not responsible.

Twenty-Seventh Additional Defense

27. Plaintiff's claim for breach of implied warranties is barred because the Plaintiff failed to rely on any warranty by or from Defendant.

Twenty-Eighth Additional Defense

28. Plaintiff's claim for breach of implied warranties is barred because any alleged warranty was disclaimed.

Twenty-Ninth Additional Defense

29. Plaintiff's negligence claims are barred by Defendant's written disclaimers of liability.

Thirtieth Additional Defense

30. Defendant is entitled to the benefit of the provisions concerning the “[e]ffect of release or covenant not to sue in respect to liability and contribution” contained in Virginia Code § 8.01-35.1.

Thirty-First Additional Defense

31. Defendant reserves the right to amend and add other defenses that become apparent through discovery of the evidence.

WHEREFORE, having fully answered the plaintiff’s Complaint, defendant Medtronic, Inc. respectfully prays for relief and judgment against the plaintiff as follows:

- A. That Plaintiff take nothing by reason of the Complaint;
- B. That this action be dismissed with prejudice;
- C. That Medtronic recover its fees, costs and attorneys’ fees incurred herein; and
- D. Such further and other relief as the Court deems proper.

Respectfully submitted,

MEDTRONIC, INC.

By B. D. Fowler

Counsel

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Counsel for Medtronic, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this 11th day of January, 2005, I electronically filed the foregoing with the Clerk of the court using the CM/ECF system which will send notification of such filing to:

Robert B. Adams, Esquire
GAMMON & GRANGE, P.C.
8280 Greensboro Drive, 7th Floor
McLean, Virginia 22102

Counsel for Plaintiff

and I hereby certify that on this 11th day of January, 2005, I have mailed by United States Postal Service the document to the following:

Robert B. Adams, Esquire
Timothy R. Obitts, Esquire
GAMMON & GRANGE, P.C.
8280 Greensboro Drive, 7th Floor
McLean, Virginia 22102

Counsel for Plaintiff


